

110TH CONGRESS  
2D SESSION

# H. R. 6151

To amend the Federal Food, Drug, and Cosmetic Act with respect to drug and device advertising, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

MAY 22, 2008

Ms. DELAURO (for herself and Mrs. EMERSON) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to drug and device advertising, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Responsibility in Drug  
5 and Device Advertising Act of 2008”.

6 **SEC. 2. DIRECT-TO-CONSUMER DRUG OR DEVICE ADVER-**  
7 **TISING.**

8 (a) IN GENERAL.—The Federal Food, Drug, and  
9 Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

1 (1) in section 301, by adding at the end the fol-  
2 lowing:

3 “(oo) The conduct of direct-to-consumer advertising  
4 of a drug or device in violation of section 503C.”; and

5 (2) in chapter V, by inserting after section  
6 503B the following:

7 **“SEC. 503C. DIRECT-TO-CONSUMER DRUG OR DEVICE AD-  
8 VERTISING.**

9 “(a) PROHIBITIONS.—

10 “(1) FIRST THREE YEARS.—

11 “(A) IN GENERAL.—Subject to subpara-  
12 graph (B), no person shall conduct direct-to-  
13 consumer advertising of—

14 “(i) a drug for which an application is  
15 submitted under section 505(b) before the  
16 end of the 3-year period beginning on the  
17 date of the approval of such application; or

18 “(ii) a class II or class III device for  
19 which a premarket notification is sub-  
20 mitted under section 510(k) or a class III  
21 device for which a premarket approval is  
22 sought under section 515, before the end  
23 of the 3-year period beginning on the date  
24 of the notification or approval, respectively.

1           “(B) WAIVER.—The Secretary may waive  
2 the application of subparagraph (A) to a drug  
3 or device during the third year of the 3-year pe-  
4 riod described in such subparagraph if—

5                   “(i) the sponsor of the drug or device  
6 submits an application to the Secretary  
7 pursuant to subparagraph (C); and

8                   “(ii) the Secretary, after considering  
9 the application and any accompanying ma-  
10 terials, determines that direct-to-consumer  
11 advertising of the drug or device would  
12 have an affirmative value to public health.

13           “(C) APPLICATION FOR WAIVER.—To seek  
14 a waiver under subparagraph (B), the sponsor  
15 of a drug or device shall submit an application  
16 to the Secretary at such time, in such manner,  
17 and containing such information as the Sec-  
18 retary may require.

19           “(2) SUBSEQUENT YEARS.—

20                   “(A) EXTENSION OF PROHIBITION.—The  
21 Secretary may prohibit direct-to-consumer ad-  
22 vertising of a drug or a class II or class III de-  
23 vice during the period beginning at the end of  
24 the 3-year period described in paragraph (1)(A)  
25 if the Secretary determines that the drug or de-

1 vice has significant adverse health effects based  
2 on post-approval studies, risk-benefit analyses,  
3 adverse event reports, the scientific literature,  
4 any clinical or observational studies, or any  
5 other appropriate resource.

6 “(B) FAIR BALANCE OF BENEFITS AND  
7 RISKS FOR DRUGS AND DEVICES FOR PER-  
8 MITTED DTC ADVERTISING.—Any direct-to-con-  
9 sumer advertising of a drug or a class II or  
10 class III device permitted under this section  
11 shall include a fair balance, as supported by the  
12 evidence, of the benefits and the risks associ-  
13 ated with the drug or device.

14 “(b) REGULATIONS.—Not later than 1 year after the  
15 date of the enactment of this section, the Secretary shall  
16 revise the regulations promulgated under this Act gov-  
17 erning advertisements of drugs and devices to the extent  
18 necessary to implement this section.

19 “(c) RULE OF CONSTRUCTION.—This section shall  
20 not be construed to diminish the authority of the Secretary  
21 to prohibit or regulate direct-to-consumer advertising of  
22 drugs or devices under other provisions of law.”.

23 (b) EFFECTIVE DATE.—The amendments made by  
24 subsection (a) apply only with respect to a drug for which  
25 an application is approved under section 505(b) of the

1 Federal Food, Drug, and Cosmetic Act, a class II or class  
2 III device for which a notification is submitted under sec-  
3 tion 510(k) of such Act, or a class III device for which  
4 an application is approved under section 515 of such Act,  
5 on or after the date that is 1 year before the date of the  
6 enactment of this Act.

7 **SEC. 3. PROMINENT DISPLAY OF INFORMATION IN ADVER-**  
8 **TISING ON SIDE EFFECTS, CONTRAINDICA-**  
9 **TIONS, AND EFFECTIVENESS.**

10 (a) REQUIREMENT FOR DRUGS.—

11 (1) IN GENERAL.—Subparagraph (3) of section  
12 502(n) of the Federal Food, Drug, and Cosmetic  
13 Act (21 U.S.C. 352(n)) is amended—

14 (A) by striking “such other information”  
15 and all that follows through “which shall be  
16 issued by” and inserting “such other informa-  
17 tion in brief summary relating to side effects,  
18 contraindications, and effectiveness as shall be  
19 required in regulations which shall require such  
20 information to be prominently displayed in  
21 terms of font size and location and shall be  
22 issued by”;

23 (B) by striking “in the case of published  
24 direct-to-consumer advertisements” and insert-  
25 ing “in the case of direct-to-consumer advertise-

1           ments (including an advertisement that accom-  
2           panies video programming delivered by tele-  
3           vision broadcasting or by a multichannel video  
4           programming distributor (as defined in section  
5           602 of the Communications Act of 1934))”;  
6           and

7                   (C) by striking “published after the effec-  
8           tive date” and inserting “disseminated after the  
9           effective date”.

10           (2) DISCONTINUANCE OF STUDY.—The Sec-  
11           retary of Health and Human Services shall dis-  
12           continue the study required by section 906(b) of the  
13           Food and Drug Administration Amendments Act of  
14           2007 (Public Law 110–85).

15           (b) APPLICATION OF SIMILAR RULES FOR DE-  
16           VICES.—The first sentence of section 502(r) of the Fed-  
17           eral Food, Drug, and Cosmetic Act (21 U.S.C. 352(r))  
18           is amended—

19                   (1) by striking “(1) a true statement” and in-  
20           serting “a true statement (1)”;

21                   (2) by striking “a brief statement”; and

22                   (3) by inserting before the period at the end the  
23           following: “, and in the case of direct-to-consumer  
24           advertisements (including an advertisement that ac-  
25           companies video programming delivered by television

1 broadcasting or by a multichannel video program-  
2 ming distributor (as defined in section 602 of the  
3 Communications Act of 1934)) the following state-  
4 ment printed in conspicuous text: ‘You are encour-  
5 aged to report negative side effects of medical de-  
6 vices to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or  
7 call 1–800–FDA–1088.’”.

8 (c) EFFECTIVE DATE.—The amendments made by  
9 this section apply with respect to any advertisement or  
10 other descriptive printed matter that is issued or caused  
11 to be issued on or after the date that is 90 days after  
12 the date of the enactment of this Act. Not later than 90  
13 days after the date of the enactment of this Act, the Sec-  
14 retary shall revise any regulations promulgated pursuant  
15 to subsections (n) and (r) of section 502 of the Federal  
16 Food, Drug, and Cosmetic Act (21 U.S.C. 352) to the ex-  
17 tent necessary to implement this section.

18 **SEC. 4. CIVIL PENALTY.**

19 Subsection (g) of section 303 of the Federal Food,  
20 Drug, and Cosmetic Act (21 U.S.C. 333) is amended to  
21 read as follows:

22 “(g) DRUG OR DEVICE ADVERTISING AND PRO-  
23 MOTION.—

24 “(1) CIVIL PENALTY.—

1           “(A) IN GENERAL.—Any manufacturer,  
2           packer, or distributor of a drug or device who  
3           violates section 505(n), section 503C, or any  
4           other requirement of this Act relating to the ad-  
5           vertising or promotion of the drug or device  
6           shall be subject to a civil penalty in an amount  
7           not to exceed—

8                   “(i) in the case of the first such viola-  
9                   tion by the manufacturer, packer, or dis-  
10                  tributor relating to the drug or device,  
11                  \$1,000,000; and

12                  “(ii) in the case of each subsequent  
13                  violation by the manufacturer, packer, or  
14                  distributor relating to the drug or device,  
15                  an amount that is twice the amount of the  
16                  maximum civil penalty applicable under  
17                  this subparagraph to the previous viola-  
18                  tion.

19           “(B) PROCEDURE.—Paragraphs (3)  
20           through (5) of subsection (f) shall apply with  
21           respect to a civil penalty under subparagraph  
22           (A) to the same extent and in the same manner  
23           as those paragraphs apply with respect to a  
24           civil penalty under paragraph (1), (2), (3), or  
25           (4) of subsection (f).

1           “(2) DISTRIBUTION OF MATERIALS.—If the  
2 Secretary finds that a person committed a violation  
3 described in paragraph (1)(A), the Secretary may  
4 order the person to distribute materials in the same  
5 markets in which the violative advertisement or pro-  
6 motional material was distributed in a manner de-  
7 signed to notify the public and the medical commu-  
8 nity of the violation and to provide corrective infor-  
9 mation.

10           “(3) SEPARATE OFFENSE.—For purposes of  
11 imposing a civil penalty under this subsection, each  
12 violation described in paragraph (1)(A), including  
13 each distribution of a direct-to-consumer advertise-  
14 ment in violation of section 503C, shall constitute a  
15 separate offense.

16           “(4) RELATION TO OTHER PENALTIES.—A civil  
17 penalty under paragraph (1) and an order under  
18 paragraph (2) shall be in addition to any other pen-  
19 alty applicable under this Act or other law to the  
20 violation involved.”.

21 **SEC. 5. PUBLIC EDUCATION CAMPAIGN ON RISKS OF CER-**  
22 **TAIN DRUGS AND DEVICES.**

23           The Secretary of Health and Human Services shall  
24 conduct an education campaign to increase public aware-  
25 ness of risks that, for some patients, may outweigh the

1 benefits of using a particular drug or device, whether such  
2 risks are known at the time of the approval of the drug  
3 or device or become known after the approval of the drug  
4 or device.

5 **SEC. 6. ADDITIONAL FUNDING FOR REGULATION OF DI-**  
6 **RECT-TO-CONSUMER DRUG AND DEVICE AD-**  
7 **VERTISING.**

8 There are authorized to be appropriated to the Food  
9 and Drug Administration such sums as may be necessary  
10 for each of fiscal years 2009 and 2010 for the purpose  
11 of regulating direct-to-consumer drug and device adver-  
12 tisements, including by carrying out the amendments  
13 made by section 2. The authorization of appropriations in  
14 the preceding sentence is in addition to any other author-  
15 ization of appropriations for such purpose.

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